DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-766/S-007

HLR Technology Corporation
Attention: Margaret J. Jack
Program Director
340 Kingsland Street
Nutley, New Jersey 07110-1199

Dear Ms. Jack:

Please refer to your supplemental new drug application dated November 28, 2000, received November 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xenical (orlistat) Capsules.

This "Changes Being Effected" supplemental new drug application provides for changes regarding the Xenical-pravastatin interaction study to the ***Drug Interactions*** subsection of the **PRECAUTIONS** section of the package insert. Specifically, this supplement deletes the statement that Xenical induces a modest increase in the bioavailability and lipid-lowering effect of pravastatin. The new information states that Xenical did not affect the pharmacokinetics of pravastatin. Corresponding changes were also made in the *Drug-Drug Interactions* sub-section of the **CLINICAL PHARMACOLOGY** section.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted November 28, 2000). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic
and Endocrine Drug Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research